Outside Start Cilostazol Bridge Study (Outpatient peri-Surgical Interruption of Drug Eluting Stent Antiplaletet Regimen Testing A Cilostazol Bridge Study): A 6 year experience

Charles L. Laham,1 Michael S. Chandra,2 Nicolas W. Shamas3
1Holy Family Memorial Hospital, Manitowoc, WI; 2University of this study. Core laboratories were utilized for independent confirmation of angiography and duplex ultrasound findings. All site reported MAEs were adjudicated by an independent Clinical Events Committee.

RESULTS For the BIOFLEX-I study of patients with iliac disease treated with the Astron stent, the primary endpoint was met. The 12-month composite endpoint of MAE was 2.1% (3/146) (p = 0.0035) CI [0.4, 5.9]. The 30-day mortality rate was 0.7% (1/146) 95% CI [0.0, 3.8]. Target lesion revascularization (TLR) rates at 12 months were 1.4% (2/146) 95% CI [0.2, 4.5], and 12-month index limb amputation was 0.0% (0/146) 95% CI [0.0, 2.5]. The secondary endpoint of primary patency was 89.8% (125/138) 95% CI [83.3, 94.5]% at 12 months.

CONCLUSION The 12-month outcomes of the BIOFLEX-I study for the Astron stent in iliac indications demonstrate a low MAE rate, high primary patency, and a low rate of TLR. This supports the safety and efficacy of the self-expanding, nitinol stent for treatment of atherosclerotic lesions in the iliac arteries.

CPT-321
Passeo-18 Lux Drug Releasing Balloon: 12-month Update From The Biolux P-I And Biolux P-II Studies And The Biolux P-III All-comers Study Design

Marianne Brodmann,1 Thomas Zeller,2 Dierk Scheinert,3 Karl-Ludwig Schulte,4 Charles L. Laham,1 Michael S. Chandra,2 Nicolas W. Shamas3
1Städtische Kliniken Neuss, Lukaskrankenhaus GmbH, Neuss, Germany; 2West German Heart Center, Essen, Germany; 3Kantonspital Luzern, Luzern, Switzerland; 4AZ Sint Blasius, Dendermonde, Belgium; 5Universitätsklinikum Kiel, Kiel, Germany

Purpose Drug releasing balloon (DRB) angioplasty has evolved to a paradigm shift in the endovascular treatment of peripheral artery disease (PAD). The current evidence base has been fuelled mostly by clinical trials with restrictive eligibility criteria, excluding most patients treated in daily practice.

Methods BIOLUX P-I and BIOLUX P-II were prospective, international, multicentre, first-in-human, randomized controlled trials investigating the safety and efficacy of the Passeo-18 Lux DRB in the femoropopliteal and infrapopliteal arteries, respectively. BIOLUX P-III is a global, prospective, international, multicentre, all-comers study to enroll at least 700 patients with infranigual artery lesions treated with the Passeo-18 Lux DRB. The clinical and performance primary endpoints are major adverse events at 6 months and freedom from clinically-driven target lesion revascularization at 12 months, respectively. Pre-specified analysis subgroups include: Age; Gender; Diabetes; Renal Insufficiency; Rutherford Category; Stenosis Severity; Intensity; Lesion Type; and Lesion Length.

Results BIOLUX P-III will build and expand on safety and performance outcomes from the BIOLUX P-I and BIOLUX P-II studies: BIOLUX P-I demonstrated significant differences in late lumen loss, TLR and binary restenosis in favour of the Passeo-18 Lux DRB compared to control PTA in femoropopliteal lesions. In BIOLUX P-II, Rutherford Class 5 patients with infrapopliteal lesions demonstrated significant clinical improvement at 6 months. Updated 12 month results from both studies will be presented.

Conclusion With inclusion and exclusion criteria that reflect complex, ‘real-world’ clinical practice, BIOLUX P-III will further illuminate the role of DRB, alone or in combination with other treatment modalities, in the contemporary management of patients with infranigual PAD (ClinicalTrials.gov identifier: NCT02276313).

Curt-325
Clinical Outcomes Of The BIOFLEX-I Study: Utilization Of Self Expanding Stents In The Iliac Arteries

Mark W. Burket,1 Marianne Brodmann,2 Michael R. Jaff
1University of Toledo Medical Center, Toledo, OH; 2Medical University of Graz, Graz, Austria; 3Massachusetts General Hospital, Boston, MA

BACKGROUND Percutaneous transluminal angioplasty has historically been the standard in minimally invasive treatment of peripheral artery disease (PAD). In iliac arteries, self-expanding, nitinol stent technology has evolved as an effective treatment. BIOLUX P-III will evaluate the safety and efficacy of the Astron stent in the iliac arteries.

METHODS The BIOFLEX-I study was a prospective, multicenter, non-randomized, single arm, investigational device exemption (IDE) study performed in the United States, Canada, and Europe. Thirty (30) study centers enrolled 161 evaluable study subjects for treatment of de novo or restenotic lesions (<140mm length) or occlusions (>100mm length) in common and/or external iliac arteries with reference vessel diameters from 6 to 10mm. The primary endpoint was the composite rate of procedure or stent related major adverse events (MAEs) at 12 months post index procedure. MAEs were defined as 30-day mortality, clinically-directed target lesion revascularization (TLR) and index limb amputation at 12 months. Results were compared to a pre-specified performance goal based on prior prospective, multicenter studies utilizing drug releasing, self-expanding stents for the treatment of iliac lesions similar to those in this study. Core laboratories were utilized for independent confirmation of angiography and duplex ultrasound findings. All reported MAEs were adjudicated by an independent Clinical Events Committee.

RESULTS For the BIOFLEX-I study of patients with iliac disease treated with the Astron stent, the primary endpoint was met. The 12-month composite endpoint of MAE was 2.1% (3/146) (p = 0.0035) CI [0.4, 5.9]. The 30-day mortality rate was 0.7% (1/146) 95% CI [0.0, 3.8]. Target lesion revascularization (TLR) rates at 12 months were 1.4% (2/146) 95% CI [0.2, 4.5], and 12-month index limb amputation was 0.0% (0/146) 95% CI [0.0, 2.5]. The secondary endpoint of primary patency was 89.8% (125/138) 95% CI [83.3, 94.5]% at 12 months.

CONCLUSION The 12-month outcomes of the BIOFLEX-I study for the Astron stent in iliac indications demonstrate a low MAE rate, high primary patency, and a low rate of TLR. This supports the safety and efficacy of the self-expanding, nitinol stent for treatment of atherosclerotic lesions in the iliac arteries.

CPT-328
Long Term Clinical Data Of The BIOSOLVE-I Study With The Pciatxel-eluting Absorbable Magnesium Scaffold (DREAMS) And Multi-modality Imaging Analysis

Michael Haude,1 Raimund Erbel,2 Paul Erne,3 Stefan Verheye,4 Paul Vermeersch,4 Emma von Andrian,5 Hubertus Degen,6 Dirk Bose,3 Ron Waksman,7 Neil J. Weissman,8 Francesco Prati,9 Jacques Koolen2
1Medical University of Graz, Graz, Austria; 2Universitäts-Herzzentrum Freiburg Bad Krozingen, Bad Krozingen, Germany; 3Universitätsklinikum Leipzig, Leipzig, Germany; 4Ev. Krankenhaus Koenigstein Elizabeth Herzberger, Berlin, Germany; 5AZ Sint Blasius, Dendermonde, Belgium; 6Imelda Zierkenhuis, Ronshoend, Belgium; 7Universitätsklinikum für Radiodiagnostik, AKH Wien, Vienna, Austria; 8RoMed Klinikum Rosenheim, Rosenheim, Germany

Purpose Drug releasing balloon (DRB) angioplasty has evolved to a paradigm shift in the endovascular treatment of peripheral artery disease (PAD). The current evidence base has been fuelled mostly by clinical trials with restrictive eligibility criteria, excluding most patients treated in daily practice.

Methods BIOLUX P-I and BIOLUX P-II were prospective, international, multicentre, first-in-human, randomized controlled trials investigating the safety and efficacy of the Passeo-18 Lux DRB in the femoropopliteal and infrapopliteal arteries, respectively. BIOLUX P-III is a global, prospective, international, multicentre, all-comers study to enroll at least 700 patients with infranigual artery lesions treated with the Passeo-18 Lux DRB. The clinical and performance primary endpoints are major adverse events at 6 months and freedom from clinically-driven target lesion revascularization at 12 months, respectively. Pre-specified analysis subgroups include: Age; Gender; Diabetes; Renal Insufficiency; Rutherford Category; Stenosis Severity; Intensity; Lesion Type; and Lesion Length.

Results BIOLUX P-III will build and expand on safety and performance outcomes from the BIOLUX P-I and BIOLUX P-II studies: BIOLUX P-I demonstrated significant differences in late lumen loss, TLR and binary restenosis in favour of the Passeo-18 Lux DRB compared to control PTA in femoropopliteal lesions. In BIOLUX P-II, Rutherford Class 5 patients with infrapopliteal lesions demonstrated significant clinical improvement at 6 months. Updated 12 month results from both studies will be presented.

Conclusion With inclusion and exclusion criteria that reflect complex, ‘real-world’ clinical practice, BIOLUX P-III will further illuminate the role of DRB, alone or in combination with other treatment modalities, in the contemporary management of patients with infranigual PAD (ClinicalTrials.gov identifier: NCT02276313).